

## APPARATUS AND METHOD OF FERTILITY AWARENESS

### RELATED APPLICATION INFORMATION

This application claims priority from United States Provisional Application Serial 5 No. 60/448,677 entitled "APPARATUS AND METHOD OF FERTILITY AWARENESS" filed on February 20, 2003, the entire disclosure of which is hereby incorporated herein.

### FIELD OF THE INVENTION

10 The present invention relates generally to natural family planning methods, and more particularly to providing visual indications relating to various phases of a woman's menstrual cycle.

### BACKGROUND OF THE INVENTION

15 A normal woman's menstrual cycle has three general phases, namely, 1) a phase when the woman experiences menstrual bleeding; 2) a phase when a woman discharges cervical mucus and ovulates; and 3) a phase when the ovulated egg has died and the cervical mucus has dried up. In phase 1 (the menses phase), the woman is in a phase of unlikely fertility. When the woman is in phase 2 (the fertile phase), the woman is in a 20 phase of possible fertility. When the woman is in phase 3 (the infertile phase), the woman is in a phase of complete infertility.

There are a number of natural family planning systems that have been developed and are being used successfully by women and couples. However, there are limitations methodologically and educationally to each of these systems. Despite the availability of 25 existing natural family planning systems, only 2 percent of couples in the United States and 5 percent world wide use natural means of birth regulation. In this context, there is a need for more "user friendly" systems that reflect current scientific evidence in regard to natural family planning and present the continuum of natural family planning use.

Existing sympto-thermal systems integrate mucus observations with post-30 ovulatory temperature changes. However, recent studies suggest that the correlation of biphasic temperature changes to ovulation is accurate in only 70 percent of cases.

Sympto-thermal methods are also dependent upon written literacy in which women are able to comfortably read a thermometer, chart temperatures and interpret the temperature pattern. This level of written literacy may be difficult to achieve in many areas of the world, effectively precluding sympto-thermal NFP system use.

5 Existing ovulation methods rely solely on mucus observations and interpretations. In this way, they can be accessible to both literate and non-literate users. However existing mucus only methods are based upon data that may not accurately reflect day specific pregnancy probabilities. By recommending abstinence during vaginal bleeding and emphasizing the use of "dry days" before ovulation, such methods may increase  
10 surprise pregnancy rates. Such pre-ovulatory surprise pregnancy rates have been documented in the World Health Organization data that examined ovulation method effectiveness.

15 A recently developed method of natural family planning (The Standard Days Method) holds promise as a simplified method of fertility awareness. While the method relies on day-specific pregnancy probabilities, it is limited to use in women with regular cycles from 26 to 32 days.

20 Finally, there is a need to make natural family planning relevant culturally and generationally. Within the United States and Europe, there is interest in natural, non-hormonal and non-invasive means of medical and reproductive health care. At the same time, women and couples of reproductive age, have grown up accustomed to technological interventions and instrumentations as a part of every day life. Meanwhile, in the developing world, women and couples may have a wide range of educational backgrounds. For example, in Africa as a whole, only 40 percent of women are considered literate. In the context of widespread illiteracy, there is a need for family  
25 planning systems that are simple, visual and can be used by all women and couples, regardless of their educational background.

#### SUMMARY OF THE INVENTION

30 Accordingly, the present invention provides a method and apparatus for tracking the menses phase, the fertility phase and the infertile phase during a woman's menstrual

cycle. This method and apparatus are used to indicate when a woman may be more likely to become pregnant. Thus, this method and apparatus can be used when a woman wants to become pregnant and also by a woman who wants to avoid pregnancy.

5 The method of the present invention generally involves stringing different types of beads on a string to visually indicate the phase in which the woman is in during her menstrual cycle. Different types of beads are provided for each of the three phases. In a preferred embodiment, red beads are used to indicate the menses phase, green beads are used to indicate the fertile phase and yellow beads are used to indicate the infertile phase.

10 In accordance with the present invention, a woman starts stringing a red colored bead at the beginning of her menses phase, shifts to a green colored bead when in the fertile phase, and shifts to a yellow bead when in the infertile phase. A woman seeking to become pregnant would try to have intercourse when in the fertile phase, and thus when the green beads associated with this phase are being strung on the string. On the other 15 hand, a woman seeking not to become pregnant would have intercourse preferably during the infertile phase when yellow beads are being used and when the ovulated egg has died and cervical mucus has dried up.

20 The present invention is used by a woman to visually indicate what phase the woman is in during her menstrual cycle. As stated above, the first red bead is placed on the string when the woman has begun her menses. Successive red beads are then placed on the string, one for each successive day, until there is a cross-over to the fertile phase during which the woman discharges cervical mucus and ovulates. At this point, a cross-over bead is strung on the string. The cross-over point is typically determined by the woman's knowledge of her own fertility cycle. For example, the cross-over bead is typically placed on the string anywhere from three red beads to six red beads into the 25 menstrual cycle, depending on the woman's knowledge of her own menstrual cycle. Once the fertile phase is entered, then a green bead is placed on the string to indicate the woman is in the fertile phase. The number of days in this phase are indicated by placing beads on the string, one for each day. During this period, the woman observes her cervical mucus. If the mucus is clear, not white or yellow, and is slippery and wet when 30 touched, then the woman is in phase two, the fertile phase.

It is also contemplated that during the fertile phase that the woman might use an ovulation prediction kit which detects a hormone called luteinizing hormone (LH). It is known that when the level of LH measured in a woman's blood peaks, ovulation occurs within 24-36 hours after this peak. Urine based ovulation prediction kits are available

5 which detect a critical value of LH in a woman's urine. It is well-known that the LH surge is detectable in her urine approximately four to six hours after the LH peaks in her blood. A special bead is placed on the string indicating when the LH surges. This serves as a guide to help a woman and couple identify when ovulation will occur. The ovulation kit is used generally when a woman wants to become pregnant. It also assists a couple in

10 learning the method by giving them an additional sign that they are in the possibly fertile phase of the menstrual cycle.

At some point during the woman's menstrual cycle, the cervical mucus will begin to "dry up," becoming stickier, less viscous and less clear. A special type of bead - the "Drying Up Bead" - is placed on the string on the first day the cervical mucus changes

15 from egg white and begins to dry up. This is followed by additional drying up beads (typically three) - one for each day that cervical mucus is drying up. Next, another special type of bead, which in one embodiment is a "yellow diamond" bead, is placed on the string to indicate the beginning of the infertile phase. Thereafter, yellow color beads are then placed on the string to indicate the woman is in the infertile phase. This

20 continues until the menses phase begins, at which point the process is repeated.

These and other aspects and advantages of the present invention will be apparent upon review of the following Detailed Description when taken in conjunction with the accompanying figures.

25 **DESCRIPTION OF THE DRAWINGS**

For a more complete understanding of the present invention and further advantages thereof, reference is now made to the following Detailed Description, taken in conjunction with the drawings, in which:

FIGS. 1A-B are a flowchart showing the steps involved in one embodiment of a

30 method of providing visual indications relating to various phases of a woman's menstrual cycle in accordance with the present invention; and

FIG. 2 is shows one embodiment of an apparatus for providing visual indications relating to various phases of a woman's menstrual cycle in accordance with the present invention.

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#### DETAILED DESCRIPTION

FIGS. 1A-1B show the steps involved in one embodiment of a method (10) of providing visual indications relating to various phases of a woman's menstrual cycle. In general, the method (10) involves placing a bead on a string during each day of the 10 woman's menstrual cycle. Different types of beads are utilized to provide indications of the three different phases (i.e., menses, fertile and infertile phase) as well as various significant events during the three phases. The method (10) may be undertaken by a woman on her own or in conjunction with another (e.g., her spouse) to monitor her menstrual cycle in order to assess the best days to engage in sexual intercourse if she 15 wants to become pregnant or to avoid sexual intercourse during certain days if she wants to avoid becoming pregnant.

One embodiment of an apparatus 200 that may be utilized in conjunction with the method (10) to provide the visual indications is illustrated in FIG. 2. In FIG. 2, the apparatus 200 is shown with the various different types of beads 220-340 as positioned 20 on a string 210 at the completion of the woman's menstrual cycle to provide the desired visual indications throughout the progression of the woman's menstrual cycle. In this regard, each bead 220-340 may include a hole for receiving an end of the string 210 there through. As may be appreciated, the beads 220-340 may be configured differently than depicted in FIG. 2, and the string 210 may in general be any similarly configured item 25 such as, for example, wire, fishing line, cord, rope or the like. Further, FIG. 2 illustrates placement of the beads 220-340 for a typical 28 day menstrual cycle. The total number of beads and the number of beads used for particular phases can vary depending upon a particular woman's menstrual cycle, and the method (10) and apparatus 200 are entirely appropriate for use by a woman with different duration menstrual cycles.

30 The method begins with the step (20) of placing a first type of bead on the string to indicate start of the menses phase of the woman's menstrual cycle. In this regard, the

step (20) of placing a first type of bead on the string may be performed on first day the woman experiences bright red menstrual bleeding. The first type of bead (the “Day One” bead) may, for example, be a large red bead 220 such as shown in FIG. 2.

After placing the first type of bead on the string, in step (30) additional beads are 5 placed on the string to indicate each additional day of menstrual bleeding during the menses phase. In this regard, a second type of bead may be used to differentiate the first day of the menses phase from subsequent days of the menses phase. For example, as shown in FIG. 2, small red beads 230 may be used. Though the number of second type beads placed on the string varies depending on the duration of the woman’s menses 10 phase, generally three to six second type beads are placed on the string and, in a woman with regular menstrual cycles typically four second type beads are placed on the string to indicate four additional days of the menses phase.

After the menses phase concludes (typically though not always on the sixth day after the start of the menses phase), in step (40) a third type of bead is placed on the string 15 to indicate the day the menses phase concludes and the woman’s menstrual cycle crosses into the fertile phase of the woman’s menstrual cycle. As is illustrated in FIG. 2, the third type of bead (the “Crossroads” or “Cross-over” bead) may be a large tri-color bead 240. The tri-color bead 240 includes three differently colored portions, namely a red portion 240A, a green portion 240B and a yellow portion 240C, and three corresponding holes 20 for placement of the tri-color bead 240 in one of three different orientations on the string 210. The tri-color bead 240 may be oriented on the string 210 based, for example, on observations made of the woman’s cervical mucus made in step (60) described below. In this regard, if the woman is observed as having continued menstrual bleeding, the large 25 tri-color bead 240 may be placed on the string 210 using the hole through the red portion of the bead 240 to provide an indication of continued menstrual bleeding. If the woman’s cervical mucus is observed as being dry or absent, the large tri-color bead 240 may be placed on the string 210 using the hole through the yellow portion of the bead 240 to indicate current infertility. If the woman’s cervical mucus is observed as being sticky or egg-white, the large tri-color bead 240 may be placed on the string 210 using the hole 30 through the green portion of the bead 240 to provide an indication that the woman has entered the fertile phase of her menstrual cycle.

After the Crossroads bead is placed on the string, in step (50) additional beads are placed on the string to indicate each additional day of the fertile phase. In this regard, a fourth type of bead may be used to differentiate the additional days of the fertile phase from the first day of the fertile phase when the Crossroads bead is placed on the string.

5 For example, as shown in FIG. 2, small green beads 250 may be placed on the string 210 for additional days of the fertile phase.

During at least the fertile phase (and possibly also during the menses and infertile phases or portions thereof adjacent to the fertile phase), in step (60) the woman's cervical mucus is observed to determine the day when the woman's cervical mucus begins drying up. In this regard, cervical mucus may generally be characterized as being within one of three categories: (1) dry; (2) sticky; or (3) or egg-white. Cervical mucus is characterized as being dry when cervical mucus is absent. Cervical mucus is considered to be dry when mucus cannot be seen or touched and the woman feels no wetness at her vaginal opening. Cervical mucus is characterized as sticky when the woman feels no wetness at 10 her vaginal opening but can see opaque, cloudy, non-egg white mucus and can touch mucus that is pasty, tacky, mounds up and does not stretch. Cervical mucus is characterized as being egg-white when the woman feels wetness at her vaginal opening, sees mucus of the color of uncooked raw egg-whites and can touch mucus that feels wet and slippery and is stretchy. During the fertile phase, the woman's cervical mucus 15 typically progresses from sticky, to an egg-white peak, back to sticky, and then dry. Observing this progression allows the day following the egg-white peak when the cervical mucus begins drying up to be identified.

In step (70), a fifth type of bead is placed on the string to indicate the day the woman's cervical mucus begins drying up (the "first drying up day"). In this regard, the 25 fifth type of bead (the "first drying up bead") may be a large green bead with a yellow stripe 270 as is illustrated in FIG. 2.

Following placement of the first drying up bead on the string in step (70), step (80) is undertaken. In step (80), additional beads are placed on the string to indicate each additional day that the woman's cervical mucus is drying up. In this regard, a sixth type 30 of bead may be used to differentiate the additional days during which cervical mucus is drying following the first drying up day indicated by the first drying up bead. For

example, as shown in FIG. 2, small half green/half yellow colored beads 280 may be placed on the string 210 to indicate the additional days of cervical mucus drying. Typically, as is illustrated in FIG. 2, three half green/half yellow beads 280 are placed on the string 210 to mark three additional days of cervical mucus drying following the large 5 green with yellow stripe bead 270 marking the first drying up day.

After the drying up beads are placed on the string in steps (70) and (80), step (90) is undertaken. In step (90) a seventh type of bead is placed on the string to indicate the first day of the infertile phase of the woman's menstrual cycle. The seventh type of bead may comprise a yellow diamond bead 290 such as shown in FIG. 2.

10 After step (90), step (100) is undertaken. In step (100) additional beads are placed on the string to indicate each additional day of the infertile phase of the woman's menstrual cycle. In this regard, an eighth type of bead may be used to differentiate the additional days of the infertile phase from the first day of the infertile phase indicated by the seventh type of bead. For example, as shown in FIG. 2, small yellow colored beads 15 300 may be placed on the string 210 to indicate the additional days of the infertile phase. Yellow beads 300 are placed on the string 210 until the woman's menstrual cycle begins again with bright red menstrual bleeding.

Once the woman's menstrual cycle begins again, the number, order and types of beads on the string may be recorded on a paper chart or the like in step (110) for future 20 reference. Thereafter, the beads may be removed from the string and the method (10) may be started over to provide visual indications relating to the phases of the next menstrual cycle.

During the method (10), several additional steps may be performed. During the fertile phase, step (120) may be undertaken. In step (120), a urine ovulation prediction 25 kit is utilized to determine the day when level of luteinizing hormone (LH) released by the woman's pituitary gland surges. The LH surge generally correlates with the cervical mucus peak. Thereafter, in step (130) a ninth type of the bead is placed on the string to indicate the day when LH level surges. The ninth type of bead is placed on the string during the fertile phase in addition to the fourth, fifth, or sixth type of bead placed on the 30 string in steps (50), (70), or (80). The ninth type of bead may comprise a green diamond 330 such as is illustrated in FIG. 2.

Another additional step that may be undertaken as part of the method (10) is step (140). Step (140) may be performed throughout the menses, fertile and infertile phases of the woman's menstrual cycle. In step (140) a tenth type of bead is placed on the string for each day that the woman engages in a coital act. A tenth type of bead is placed on the 5 string in addition to (and preferably behind) the other appropriate type of bead that is placed on the string for the particular day. Placing such beads on the string serves as a means of charting to assist the woman and her partner in comprehending appropriate times to engage or not engage in coital acts depending upon their desire to become or not become pregnant. The tenth type of bead may comprise a gold colored bead 340 such as 10 shown in FIG. 2.

While various embodiments of the present invention have been described in detail, further modifications and adaptations of the invention may occur to those skilled in the art. However, it is to be expressly understood that such modifications and adaptations are within the spirit and scope of the present invention.